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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,020	10/12/2001	Alan J. Magill	P66822US0 (WRAIR 98-40/46	7596

53502 7590 01/23/2006

OFFICE OF THE STAFF JUDGE ADVOCATE (SKS)
U.S. ARMY MED. RESEARCH & MATERIAL COMMAND
504 SCOTT STREET
ATTN: MCMR-JA (MS. ELIZABETH ARWINE)
FORT DETRICK, MD 21702-5012

EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/975,020	MAGILL ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5-9-05.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 4,11,12,22-25,29,30 and 32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 4,11,12,22-25,29,30 and 32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The response filed 5-9-05 has been entered into the record. Claims 1-3, 5-10, 13-21, 26-28 and 31 have been cancelled. Claims 4, 11, 12, 22-25, 29-30 and 32 are pending and under examination.

The amendment is not in compliance with 37CFR 1.121 because it does not identify the status of claims 26-28 as cancelled. Correction of this deficiency is required in response to this office action.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Any rejection not reiterated herein is withdrawn in favor of the new rejections set forth below.

New Objections/Rejections

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The term "free from dextran" lacks antecedent basis in the specification as filed. Applicants are specifically cautioned against adding new matter to the specification.

Claims 4, 11, 12, 22-30, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

It is noted that the claims recite "free of dextran". Applicants previous response filed 11-25-03 indicated that this limitation could be generally found in the description and

in the claims as originally filed. This is not persuasive, the claims as originally filed do not contain the word "dextran" much less the concept "free of dextran". The concept of "free of dextran" is not apparently provided by way of written description in the specification as filed. This issue is best resolved by Applicants pointing to the specification by page and line number where conception by way of written description can be found.

Applicants have now amended the claim to recite the functional limitation that indicate "and does not cause a false positive hypersensitivity reaction when administered to a subject". Applicants have not pointed to the specification by page and line number where written description support for this now claimed limitation can be found.

Claims 4, 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Leishmania Research project DOD-8B, or Stitler et al (Production of Leishmania Skin Test GMP Protocol requirements 1 and 2, 1994 and 1995) prior art of record.

Applicants argue that the art does not teach that the microfluidized lysate does not cause a false positive hypersensitivity reaction when administered to a subject. This is not persuasive in light of Rowton et al (45th Annual meeting of the ASTM&H, Baltimore MD, 1996) that eachtes that the MFL-LSTA skin test antigen made under GMP using the Leishmania tropic (WR1063) did not causes any response at any dose level in naïve guinea pigs (see last line). As such, the function of not causing false positives is an inherent property of the microfluidized product of the prior art. As to claim 29, the claim recites that "the microfluidized lysate "may be" frozen or freeze-dried. Since the product of the prior art is liquid, it may be either frozen or freeze-dried. The recitation of "maybe" is interpreted as "optionally" and the claim is not seen to require that the product be frozen or freeze-dried.

Claims 4, 29, 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Stitler et al, (47th Annual meeting of the ASTM&H, San Juan, PR, 1998 of record).

Stitler et al teach a heat-treated microfluidized lysate, Leishmania skin test (LSTA), reference or as MFL-LSTA [R2], where Leishmania tropic (WR#1063O) was isolated from bone marrow. Individual cryostocks were grown, harvested, washed and stored (BLP). The BLP was thawed, microfluidized, centrifuged, the supernatant was heat-treated and then sterile-filtered, the filtrate adjusted to does based upon efficacy in the guinea pig model, and then the refrigerated formulation was final container bottled. As such, the reference recites the same strain and process used in the specification (see and therefore the product of the prior art is inherently the same as the claimed product. As to claim 29, the claim recites that "the microfluidized lysate "may be" frozen or freeze-dried. Since the product of the prior art is liquid, it may be either frozen or freeze-dried. The recitation of "maybe" is interpreted as "optionally" and the claim is not seen to require that the product be frozen or freeze-dried.

Claims 11, 12 and 22-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Leishmania Research project DOD-8B, or Stitler et al (Production of Leishmania Skin Test GMP Protocol requirements 1 and 2, 1994 and 1995) or Stitler et al, (47th Annual meeting of the ASTM&H, San Juan, PR, 1998 of record) each taken in view of Reed (US/2002/0169285; of record).

Leishmania Research project DOD-8B, or Stitler et al (Production of Leishmania Skin Test GMP Protocol requirements 1 and 2, 1994 and 1995) or Stitler et al, (47th Annual meeting of the ASTM&H, San Juan, PR, 1998 of record) are each set forth above. The references differ by not including a stabilizer and not including the product in a kit with a package insert.

Reed et al teach reagents for diagnostic skin testing for Leishmaiasis and indicate that the current skin tests typically use whole or lysed parasites (paragraphs [0002] and

[0005]). Reed et al teach that reagents for performing the method can be included in a diagnostic kit comprising the antigen and an apparatus for applying the antigen([0013]). Reed et al aslo teach the hypersensitivity response from the reagent can be determined using a ruler. Reed et al teach that antigen for the skin test reagent are preferably formulated in an amount ranging from about 1ug to 100 ug, and the carrier employed in such pharmaceutical compositions is a saline solution with appropriate preservatives such as phenol and/or Tween80™.

As to claims 11 and 12, it would have been *prima facie* obvious to substitute the skin test antigen of Leishmania Research project DOD-8B, or Stitler et al (Production of Leishmania Skin Test GMP Protocol requirements 1 and 2, 1994 and 1995) or Stitler et al, (47th Annual meeting of the ASTM&H, San Juan, PR, 1998 of record) in the kit of Reed et all because each of Leishmania Research project DOD-8B, or Stitler et al (Production of Leishmania Skin Test GMP Protocol requirements 1 and 2, 1994 and 1995) or Stitler et al, (47th Annual meeting of the ASTM&H, San Juan, PR, 1998 of record) describe Leishmania skin test agents and Reed et al teach that such agents are conventionally packaged in a diagnostic test kit. Please note ,with respect of the kits of claims 11 and 12, The "directions" do not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert and the product, composition, or article of manufacture. See *In re Haller* 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of *In re Haller*, it is stated that: Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned...In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be *new*. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on

the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statues make no provision for patenting of an article or composition which is not, in and of itself, new. Also see *In re Venezia* 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, *In re Miller 164 USPQ 46 (CCPA 1969)* and *In re Gulak (CA FC)217 USPQ 401* relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles. The proteins of the claimed articles remain fully functional absent the labeling or printed instructions for use. It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in a kit or article manufacture constitute an "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963) In the instant case, the claims are drawn to an article of manufacture which comprises an microfluidized lysate and directions for use. The directions for use seen as intended use and are not placed on any particular article of

manufacture and therefore any article can bear such instructions. As such, the additional article of the kit of Reed in the article as combined supra is seen to meet the limitation of a second article in the kit an it may recite such instructions.

As to claims 22-25, it would been prima facie obvious to formulate the microfluidized lysate of Leishmania Research project DOD-8B, or Stitler et al (Production of Leishmania Skin Test GMP Protocol requirements 1 and 2, 1994 and 1995) or Stitler et al, (47th Annual meeting of the ASTM&H, San Juan, PR, 1998 of record) in a saline solution with appropriate preservatives such as phenol and Tween 80 because Reed et al teach that Leishmania skin test pharmaceutical compositions are conventionally so formulated with this carrier.

Status of Claims

All pending claims stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to

reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy

Primary Examiner

Art Unit 1645